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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/096,749	06/12/1998	SHOHEI KOIDE	109.034US1	2169

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/096,749

Applicant(s)

KOIDE, SHOHEI

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 29. 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. The request filed on 11/26/02 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/096749 is acceptable and a RCE has been established. Claims 1-2, 4-6 are pending and are currently under prosecution. An action on the RCE follows.
2. Claims 1-2, 4-6 have been amended.
3. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.
4. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

5. The rejection of claims 1-2, 4-6 under 35 U.S.C. 112, first paragraph for new matter is withdrawn in view of the amendments to the claims.
6. The rejection of claims 1-2, 4-6 under 35 U.S.C. 103(a) as being unpatentable over Main et al (Cell 71:671-678, 1992, IDS #5) and further in view of Lee et al (Protein Engineering 6:745-754, 1993, IDS # 8) is withdrawn in view of arguments.
7. The rejection of claims 1-2, 4-6 under 35 U.S.C. 112, first paragraph is withdrawn in view of arguments.

The following are some NEW GROUNDS of rejection Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1642

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-2, 4-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims encompass a myriad of monobodies with any sequence of two to 25 inserted amino acids, at least two deleted amino acids, or replacement of at least two amino acids in any loop sequence in the monobody. The specification does not describe the multitude of residues that are insertions, deletions, or replacements required by the claims to produce such monobodies or to produce such monobodies that form a specific binding partner with the monobody. In addition the specification does not describe the multitude of SBPs that the monobody could bind to or required to bind to. Therefore, one would reasonably conclude that applicant was not in possession of the claimed invention at the time of filing.

10. Claims 1-2, 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a monobody comprising at least two Fn3 beta strands with a loop linked between them wherein the monobody loop region sequence varies from the wild type by insertion of 3 to 25 amino acids or replacement of at least

Art Unit: 1642

two amino acids, does not reasonably provide enablement for a monobody with deletions of at least two amino acids in the loop. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to a monobody wherein the loop region varies from the wild type Fn3 loop by deletion of at least two amino acids. The claims encompass deletion of all of the amino acids in the loop. The specification discloses insertions and replacements in the loops. The specification does not enable deletions of at least two amino acids, which encompasses all amino acids in the loop, wherein the monobody binds to a SBP.

As evidenced from Burgess et al (J of Cell Biology 111:2129-38, 1990), Lazar et al (Molecular and Cellular Biology 8:1247-1252, 1988), Schwartz et al (PNAS 84:6408-11, 1987) already made of record protein chemistry is probably one of the most unpredictable areas of biotechnology. It is unpredictable which two or more residues to delete from a loop in order to obtain a protein that would bind to any SBP. The

Art Unit: 1642

specification does not enable which at least two residues to remove or if any can be removed and obtain a binding agent. Those skill in the art would readily conclude that deletion of all of the residues in a loop between two beta strands would not result in a protein that would bind to any SBP.

Conclusions

11. No Claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.
13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.